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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/548,998	04/14/2000	Richard C. Ebersole	BC1002 US NA	7991

23906 7590 03/26/2003

E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
BARLEY MILL PLAZA 25/1128
4417 LANCASTER PIKE
WILMINGTON, DE 19805

EXAMINER	
LOEB, BRONWEN	

ART UNIT	PAPER NUMBER
1636	27

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/548,998	Applicant(s) EBERSOLE ET AL.	
	Examiner Bronwen M. Loeb	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 11&25* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Revised Notice to Comply* .

DETAILED ACTION

This action is in response to the amendment filed 2 January 2003 in which claims 2 and 4 were cancelled.

Claims 1, 3 and 5 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group VIII, claims 1, 3 and 5 as they read on SEQ ID No. 8, in Paper No. 26 is acknowledged.

Sequence Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers. These sequences include **the sequence on p. 29, line 23**. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

3. A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office because

mail sent to this zip code is destined for irradiation. Computer readable formats, such as disks and CD's, are destroyed as a result of the irradiation process. The following information is also provided on the website.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)

2. Mailed to:
U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
Arlington, VA 22202

3. Mailed by Federal Express, United Parcel Service or other delivery service to:
U. S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Box Sequence
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

4. Hand Carried directly to the Customer Window at:
2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03, Box Sequence,
Arlington, Virginia 22202

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 20, line 10). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The disclosure is objected to because of the following informalities: The Brief Description of Figure 1 refers to "DHE-195" however this strain is not listed anywhere in

Figure 1. Also there is no explanation as to what "DHE. (cornell)" is (it is listed in Figure 1).

It is unclear if the "signature regions" described on p. 11, line 12-14 are the same, different or related to the "signature groups" referred to in Table 2 and p. 27, lines 7-15.

Appropriate correction is required.

Claim Objections

6. Claim 1 is objected to because of the following informalities: Claim 1 recites non-elected subject matter (SEQ ID Nos. 1-6, 30 and 34). Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3 and 5 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the

invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

This rejection is based on the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 1 is drawn to an isolated 16S rDNA sequence indicative of a dechlorinating bacterial strain which is an isolated nucleic acid molecule that has the sequence of SEQ ID No. 8, that hybridizes to SEQ ID No. 8 under specific hybridization conditions or is completely complementary to either of the above. This is a genus claim in terms of any nucleic acid that has a sequence as specified by SEQ ID No. 8 (since there are seven positions, each of which may be one of two deoxynucleotides, SEQ ID NO. 8 is itself a genus encompassing 2^7=128 species), any nucleic acid that hybridizes to SEQ ID No. 8 under these conditions or any nucleic acid that is completely complementary to either of the above. The specification mentions SEQ ID No. 8 and seven positions therein that vary among dechlorinating bacterial strains. This disclosure

is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all hybridizing nucleic acids based on the teachings in the specification. The specification teaches that in a 16S rDNA profile defined by the comparison of isolated dechlorinators, SEQ ID No. 8 is one of four signature regions that show considerable variations from the known sequences. The specification further teaches that "although a region similar to that defined by SEQ ID No. 8 is found in the literature sequence, there are significant variations at positions E184, E190, E197, E200, E207, E216 and E221" although the sequence shown actually has variable positions labelled as E184, E190, E198, E201, E208, E217 and E222 (p. 11, lines 28-34). Other than the various specific nucleotides at these 7 positions, the specification does not teach *any* other position variation that may occur within SEQ ID No. 8 that remains indicative of dechlorinating bacterial strains. Furthermore, the specification fails to teach whether these seven positions can vary independently and still remain indicative of a dechlorinating bacterial strain. For instance, in the five dechlorinating strains shown in Figure 1, when E184 is an A, E190 is always T. Thus, it is unknown if a strain in which E184 is a G and E190 is a T is indicative of a dechlorinating bacterial strain. Therefore, the specification does not describe the claimed isolated nucleic acid molecules that are the 128 species of SEQ ID No. 8. that hybridize to SEQ ID No. 8 under specific hybridization conditions or are completely complementary to either above in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these isolated nucleic acids at the

time of filing the present application. Thus, the written description requirement has not been satisfied.

9. Claims 1, 3 and 5 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the six specific sequences encompassed by the genus of SEQ ID No. 8 as being indicative of dechlorinating bacterial strains, does not reasonably provide enablement for sequences which are not indicative of dechlorinating bacterial strains. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification teaches that the use for the claimed isolated 16S rDNA sequences is for indicating whether a bacterial strain is a dechlorinator strain. There is no use taught for those nucleic acids encompassed by the claims that are, however, not indicative of a dechlorinating bacterial strain. One of skill in the art would be required to pursue a large quantity of trial and error experimentation in order to ascertain a use for each nucleic acid which is not indicative of a dechlorinating bacterial strain.

Since only the preamble recites "indicative of a dechlorinating bacterial strains, this "functional" limitation is not a patentable distinction. Amending the body of the claim to recite the functional limitation of "being indicative of a dechlorinating bacterial strain" may overcome this rejection.

10. The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 3 and 5 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite. SEQ ID No. 8 is 47 nucleotides in length; the specification teaches that it corresponds to E180 to E226. This relationship suggests that nucleotide #1 of SEQ ID No. 8 is also called "E180". The variable positions are thus E197, E200, E207,E216 and E221. In SEQ ID No. 8, E198 is G, E201 is G, E208 is T, E217 is A and E222 is G. Thus, by reciting "E198=T, E201=T, E208=C, E217=T, E222=C", claim 3 *broadens* the scope of the parent claim rather than narrowing it.

Claim 3 is also vague and indefinite in that, since SEQ ID No. 8 corresponds to E180 to E226, it is unclear how any of the other E-positions specified in claim 3 can be in SEQ ID No. 8.

Claim 5 is dependent on a cancelled claim (claim 4) rendering the metes and bounds of claim 5 uncertain.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 5 is rejected under 35 U.S.C. §102(b) as being anticipated by Maymó-Gatell et al (Science (1997) 276:1568-1571; cited in the IDS filed 7 January 2002).

Maymó-Gatell et al teach isolating a PCE-dechlorinating organism called strain 195. Assuming that strain 195 (*Dehalococcoides ethenogenes* strain 195) is the same as "DHE.(cornell)" listed in Figure 1, this isolated bacterial strain comprises one of the species of sequences encompassed by SEQ ID No. 8 and therefore anticipates claim 5. See entire article, particularly p. 1570, first column, first complete paragraph.

Conclusion

Claims 1, 3 and 5 are rejected. Claims 1 and 3 (as they read on SEQ ID No. 8) are free of prior art.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

March 21, 2003

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No.	Applicant(s)	
	09/548,998	EBERSOLE ET AL.	
	Examiner	Art Unit	
	Bronwen M. Loeb	1636	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: See Continuation Sheet

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

Continuation of Box 7: The specification recites a nucleotide sequence which lacks a sequence identifier (p. 29, line 23). If this sequence is already listed in the paper and computer readable copies of the sequence listing, amending the specification to recite the appropriate SEQ ID No. overcome the lack of compliance. If however the sequence is not already listed in the paper and computer readable copies of the sequence listing in the case, Applicant is required to provide the items indicated below. It is noted that modifications to sequences are to be described in the features (37 CFR 1.821(a)(1)) but are not to be shown explicitly in the nucleotide sequence.

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The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date	Certificate of Mailing Date
26 June 2002	20 June 2002 Paper 19

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

COPY OF PAPERS
ORIGINALLY FILED

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

Part of Paper No. 27